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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/039,307

Filing Date: October 26, 2001

Appellant(s): HILL ET AL.

Reed A. Duthler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 1/20/10 appealing from the Final Office action mailed 6/23/09 and the Advisory Action mailed 9/8/09.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner and the appellant appear to have specifications with different line spacing. For the examiner:

- The electrodes (108) are discussed on page 6, lines 3-9,
- The receiver circuit (202) and sensors (110,111) are discussed on

- page 11, lines 11-12, and on page 10, lines 20-24, respectively,
- The driver circuit (200) and processor (204) are discussed on page 10, lines 12-19 and page 11, lines 4-18,
 - Cardiac resynchronization therapy is discussed on page 8, lines 12-28, and
 - The flow charts of figures 4 and 5 are discussed on page 13, line 15 – page 14, line 14.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN REJECTIONS." New grounds of rejection (if any) are provided under the subheading "NEW GROUNDS OF REJECTION."

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant's brief.

(8) Evidence Relied Upon

5,199,428	OBEL et al.	4-1993
6,937,898	LIMOUSIN	8-2005
3,650,277	SJOSTRAND et al.	3-1972
5,792,187	ADAMS	8-1998
5,203,326	COLLINS	4-1993

(9) Grounds of Rejection

The rejection in section I. below lists Collins as a reference. The Collins reference was used to reject a limitation that is now cancelled. The Collins reference was also used in a previous comment related to the appellant's arguments, hence the Collins reference is still listed in the rejection in section I.

The following ground(s) of rejection are applicable to the appealed claim:

- I. Claims 17, 18, 20, 41, 42, 46 and 47 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,199,428 to Obel et al., hereafter Obel, and U.S. Patent No. 5,203,326 to Collins, hereafter Collins, in view of FR 2 805 469 - A1 / English translation is equivalent U.S Patent No. 6,937,898 to Limousin, hereafter Limousin.

Obel discloses an implantable electrical nerve stimulator/pacemaker for a human/ mammal, the nerves being automatically stimulated in the region of the thoracic

vertebra T2 providing electrical communication and the stimulation coordinated to resynchronization of the heart to protect the myocardium (abstract; column 1, lines 15-24; column 3, lines 8-28, 42-45; column 3, line 62 - column 4, line 26; column 5, lines 25-64).

Obel discloses pacing therapy using an anti-tachycardia pacing system (column 9, line 53 - column 10, line 2) and therapy using a back-up pacemaker (104) (column 6, line 66 - column 7, line 25) that can also provide programmable parameters and alternate pacing modes (column 8, lines 49-62). While conducting pacing therapy, the electrical stimulation is adjusted in response to one or more monitored physiological parameters (column 3, lines 8-13, 20-28).

Obel discloses cardiac therapy that decreases cardiac workload (abstract), protects the myocardial cells by reducing the oxygen demand, hence optimizing cardiac output (column 2, lines 9-13), decreases the ischemia and the potentially induced arrhythmias such as brady-arrhythmia and tachycardia (column 2, lines 59-65; column 3, lines 29-33; column 9, lines 53-57), provides pacing therapies to maintain the patient's heart rhythm within acceptable limits (column 3, lines 8-13), ameliorates myocardial ischemia and maintains adequate cardiac rate (column 3, lines 14-15), exerts a tonic effect to slow the heart down and control tachycardia (column 5, lines 5-18), and treats conditions and arrhythmias of a heart associated with coronary artery disease and myocardial insufficiency (column 10, lines 31-35), these therapy outcomes read to improve cardiac performance and efficiency of the patient's heart.

As to claims 41 and 42, Obel discloses delivering pacing therapy and electrical neural stimulation at the same time. The pacing therapy is controlled by a microprocessor based timing and control circuit such that a previously delivered pacing therapy is altered based on the sensed atrial beat (column 3, lines 8-13, 29-33; column 8, lines 49-59).

As to claims 46 and 47, Obel discloses monitoring heart rate and heart rate variability (column 3, lines 11, 44; column 6, lines 54-58).

It is noted the concepts of treating a patient to improve cardiac performance and efficiency of the patient's heart, and to improve balance of a neurological system of the patient amount to an intended use limitations of which Obel performs or is inherently capable of performing.

As discussed in the previous seven paragraphs of this action, Obel discloses the claimed invention except for the pacing therapy being cardiac resynchronization therapy.

Limousin teaches anti-tachycardia pacing therapy using cardiac resynchronization therapy for the purpose of treating and managing ventricular tachycardia. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used cardiac resynchronization therapy in the Obel system in order to provide a pacing therapy mode that is more effective in terminating organized

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ventricular tachycardia condition than previously known anti-tachycardia pacing therapies, the invention recognizing that shock therapy can be used if the resynchronization therapy is not successful to terminate the tachycardia condition (abstract; figure 1; column 1, lines 11-10, 45-50; column 2, lines 12-21; column 2, line 25 - column 3, line 2; column 4, lines 1-15).

As to a suggestion to combine the references, Obel teach pacing therapy and neural electrical stimulation to decrease the cardiac work load, optimize the cardiac cycle and cardiac output, and treat arrhythmias (abstract; column 5, lines 12-16). Collins teaches autonomic nervous system stimulation to provide therapy for abnormal heart conditions such as arrhythmias (abstract; column 6, lines 1-35). Limousin teaches cardiac resynchronization therapy to manage arrhythmias such as ventricular tachycardia (abstract). The combination of the three references is deemed appropriate and is deemed to teach the instant invention. The rejection of record stands.

The Appellant's arguments filed 4/7/09 have been fully considered, but they are not convincing. While some of the points the Appellant is trying to make are not completely clear to the Examiner, the Examiner's best understanding of the Appellant's arguments is used for the response.

The Appellant argues that:

Obel delivers nerve stimulation therapies according to pre-programmed parameters which are not varied during their delivery,

Obel may change the parameters of the nerve stimulation over time based on events prior to the current cardiac therapy, and

Obel does not adjust the nervous tissue stimulation base upon monitored physiological conditions that are monitored during resynchronization therapy.

The Examiner respectfully disagrees to all three points.

Obel does adjust the nervous tissue stimulation (first sentence of the abstract) base upon monitored physiological conditions (the condition being ischemia (first sentence of the abstract)) as monitored against the patient's coronary sinus blood ph and/or oxygen saturation and/or electrocardiogram ST elevation (column 3, lines 20-28) that are monitored during resynchronization therapy (pacing therapies are provided including back-up pacing and synchronized pacing (column 3, line 12; column 8, lines 37-47)). The Limousin reference is incorporated in rejection of record to teach cardiac resynchronization therapy (column 2, line 25 - column 3, line 2). The parameters are adjusted in real time, hence the nerve stimulation therapy is not preprogrammed, nor does it depend on events prior to the current cardiac therapy.

In response to appellant's argument that the references fail to show a certain feature of appellant's invention, it is noted that the feature upon which appellant relies (i.e., pacemaker activated non-concurrently with nerve stimulation) are not recited in the

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rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

While, as asserted by the Appellant, "the basic premise of Obel" may be "that heart pacing is only necessary during nerve stimulation due to its tendency to either slow the heart rates or trigger other arrhythmias", the Examiner is unclear what point the Appellant is seeking to make and hence the Examiner is choosing not to comment further.

II. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,199,428 to Obel et al., hereafter Obel, and U.S. Patent No. 5,203,326 to Collins, hereafter Collins, and FR 2 805 469 - A1 / English translation in equivalent U.S Patent No. 6,937,898 and Limousin, hereafter Limousin, in view of U.S. Patent No. 5,792,187 to Adams, hereafter Adams.

As discussed in paragraph II. of this action, modified Obel discloses the claimed invention except the electrode located external to the patient's body against the skin.

Adams teaches pain suppression treatment using an electrode (100) located external to the patient's body on the skin at the spine proximate to the dorsal root sensory ganglia for the purpose of relieving pain associated with the high voltage stimulation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an electrode located external to the patient's body in the

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modified Obel system in order to offer a proven treatment for the pain associated with high voltage shocks so the patient's pain, apprehension, and anxiety is controlled (abstract; figures 4; column 2, lines 48-55; column 3, lines 1-8, 45-48; column 7, lines 11-24). It is noted both electrical and electromagnetic pain suppression systems are well known in the art, and absent any teaching of criticality or unexpected results merely changing the type of system from an electromagnetic system to an electrical system would be an obvious design choice.

III. Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,199,428 to Obel et al., hereafter Obel, and U.S. Patent No. 5,203,326 to Collins, hereafter Collins, and FR 2 805 469 - A1 / English translation in equivalent U.S Patent No. 6,937,898 to Limousin, hereafter Limousin, in view of U.S. Patent No. 3,650,277 to Sjostrand et al., hereafter Sjostrand.

Obel discloses an apparatus to influence blood pressure, (column 3, lines 62-64).

As discussed in section II. of this action and in the previous paragraph, modified Obel discloses the claimed invention except using a sensor to monitor systolic blood pressure.

Sjostrand teaches blood pressure modulation using an atrial systolic blood pressure sensor to determine the level of the blood pressure. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used an atrial systolic blood pressure sensor in the modified Obel system in order to have an indication how the stimulation treatment was impacting the blood pressure, so

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appropriate changes in the treatment could be made to optimize the patient's blood pressure (abstract; column 4, line 74 - column 5, line 4).

From the advisory action mailed 9/8/09:

In response to the Appellant's arguments that the references fail to show certain features of the Appellant's invention, it is noted that the features upon which the Appellant relies (i.e., varying the programmed parameters during their delivery, varying the programmed parameters during the associated cardiac pacing therapy) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The final paragraph of independent claim 17 is read: there is a means for adjusting the electrical stimulation applied to the nerves, the stimulation of the nerves applied during delivery of the pacing therapy, the adjustments in the electrical stimulation for the nerves being responsive to the one or more physiological parameters of the patient, the parameters being monitored during delivery of the pacing therapy.

Repeating the previous reading of the final paragraph of independent claim 17 and including the citations from Obel et al.: there is a means for adjusting the electrical stimulation (60) applied to the nerves (abstract, lines 1-4; column 5, lines 45-51), the stimulation of the nerves applied during delivery of the pacing therapy (column 3, lines

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8-19; column 5, lines 25-44), the adjustments in the electrical stimulation for the nerves being responsive to the one or more physiological parameters of the patient (abstract, lines 4-13; column 3, lines 20-28, 42-45), the parameters being monitored during delivery of the pacing therapy (abstract, lines 13-18).

The Appellant asserts the new claims 54-61 were erroneously restricted as the new claims have limitations corresponding to those of the previously submitted claims, "rewritten very slightly for clarity". The Examiner respectfully disagrees. The limitations changes associated with new claims 54-61 are significant and are deemed to create a new and distinct invention. The focus in the final paragraph of the independent claim is changed from "electrical stimulation applied during delivery of the pacing therapy (to the heart)" to "electrical stimulation applied during deliver of the electrical stimulation (to the nerves)". Also a second change is made changing the limitation from "the parameters of the patient as monitored during delivery of the pacing therapy" to "parameters of the patient as monitored during contemporaneous delivery of the pacing therapy".

The rejection of record and the restriction of record stand.

(10) Response to Argument

Beginning at the top of page 6, the appellant asserts Obel does not teach a device that adjusts electrical nerve stimulation delivered during a delivered cardiac

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pacing therapy responsive to physiological parameters monitored during the delivery of the cardiac pacing therapy.

The examiner respectfully disagrees.

Obel does teach a device (60) apparatus that comprises a means to adjust electrical nerve stimulation delivered during (emphasis added) a delivered cardiac pacing therapy responsive to physiological parameters monitored during the delivery of the cardiac pacing therapy (column 3, lines 8-19; column 4, lines 11-26).

The appellant asserts the rejection violates the rules of claim interpretation and the interpretation of the claim language is not reasonable.

The examiner respectfully disagrees.

The appellant has not stated how the rejection violates the rules of claim interpretation. The rejection has been reviewed, the interpretation of the claim language has been reviewed, and the rejection of record is deemed appropriate. Lacking further information on the violation of the rules, the examiner will not comment further.

The appellant asserts the rejection is also precisely contrary to the usage of the language in the claim in the specification of the application and the interpretation of the claim language is not reasonable.

The examiner does not clearly understand the appellant's argument.

The appellant has not identified the language that is contrary. The rejection has been reviewed, the interpretation of the claim language has been reviewed, and the

rejection of record is deemed appropriate. Lacking further information on the contrary language, the examiner will not comment further.

The appellant asserts the Obel invention works contrary to the "means plus function" element in question (the final paragraph of limitations in claim 17).

The examiner respectfully disagrees.

The appellant has not identified the contrary operation in Obel. The rejection has been reviewed, the claim language has been reviewed, the specification has been review, and no operations contrary to Obel have been identified. The rejection of record is deemed appropriate. Lacking further information on the contrary operation, the examiner will not comment further.

The appellant asserts Obel does not teach varying the parameters during their delivery, and thus are not varied during the delivery of the associated cardiac pacing therapy.

The examiner respectfully disagrees.

In response to the Appellant's arguments that the references fail to show certain features of the Appellant's invention, it is noted that the features upon which the Appellant relies (i.e., varying the programmed parameters during their delivery, varying the programmed parameters during the associated cardiac pacing therapy) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

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specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The final paragraph of independent claim 17 is read: there is a means for adjusting the electrical stimulation applied to the nerves, the stimulation of the nerves applied during delivery of the pacing therapy, the adjustments in the electrical stimulation for the nerves being responsive to the one or more physiological parameters of the patient, the parameters being monitored during delivery of the pacing therapy.

Repeating the previous reading of the final paragraph of independent claim 17 and including the citations from Obel et al.: there is a means for adjusting the electrical stimulation (60) applied to the nerves (abstract, lines 1-4; column 5, lines 45-51), the stimulation of the nerves applied during delivery of the pacing therapy (column 3, lines 8-19; column 5, lines 25-44), the adjustments in the electrical stimulation for the nerves being responsive to the one or more physiological parameters of the patient (abstract, lines 4-13; column 3, lines 20-28, 42-45), the parameters being monitored during delivery of the pacing therapy (abstract, lines 13-18).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Frances P. Oropeza/
Patent Examiner, Art Unit 3766
April 20, 2010

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